

AMENDED IN ASSEMBLY AUGUST 28, 2001

AMENDED IN ASSEMBLY AUGUST 20, 2001

AMENDED IN ASSEMBLY JULY 19, 2001

SENATE BILL

No. 293

Introduced by Senator Torlakson

February 16, 2001

An act to amend Section 4123 of, and to add Article 7.5 (commencing with Section 4127) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 293, as amended, Torlakson. Pharmacies: injectable sterile drug products.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacy corporations in this state. Existing law regulates controlled substances, dangerous drugs, and dangerous devices.

This bill would create new positions within the California State Pharmacy Board in order to carry out the provisions of ~~this act~~ *the bill*. The bill would appropriate \$580,000 from the Pharmacy Board Contingent Fund for purposes of the bill.

This bill would authorize the board, based on reasonable belief obtained during an investigation or pharmacy inspection, to issue a cease and desist order to a pharmacy requiring, among other things, the pharmacy to refrain from any activity that posed an immediate threat to the public health or safety. The bill would implement quality assurance methods regarding the compounding of injectable sterile

drug products. The bill would require the board to adopt necessary regulations regarding injectable sterile drug products. The bill would require specified pharmacies to obtain a license from the board in order to prepare injectable sterile drug products. By charging a fee for these licenses which would be deposited into the continuously appropriated Pharmacy Board Contingent Fund, the bill would make an appropriation.

~~The~~

This bill would provide that a violation of ~~this act~~ *the bill* or regulations adopted pursuant to ~~this act~~ *it* would be subject to a fine of up to \$2,500. These fines would be deposited into the continuously appropriated Pharmacy Board Contingent Fund and would thereby make an appropriation.

A violation of the Pharmacy Law is a crime. By adding additional requirements to the Pharmacy Law concerning injectable sterile drug products, this bill would impose a state-mandated local program *by creating a new crime*.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: ²/₃. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature hereby establishes five
2 positions in the California State Board of Pharmacy to implement
3 the provisions of this act. Those positions shall be apportioned as
4 follows: one supervising pharmacy inspector, two pharmacy
5 inspectors, one management services technician, and one office
6 technician.

7 The sum of five hundred eighty thousand dollars (\$580,000) is
8 hereby appropriated from the Pharmacy Board Contingent Fund
9 to the California State Board of Pharmacy for the costs associated
10 with the implementation of this act, including, but not limited to,
11 the salaries and benefits of the employees described in this section.

SEC. 2. Section 4123 of the Business and Professions Code is amended to read:

4123. Any pharmacy that contracts to compound a sterile drug product for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

SEC. 3. Article 7.5 (commencing with Section 4127) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.5. Injectable Sterile Drug Products

4127. The board shall adopt regulations establishing standards for compounding sterile drug products in a pharmacy.

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. A license shall be required for each location owned or operated by a specific person where injectable sterile drug products are compounded. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4127.2. (a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. A license shall be required for each location owned or operated by a specific person or entity where injectable sterile drug products are compounded. The license shall be renewed annually.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4127.3. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that activity in a pharmacy ~~requiring a license issued pursuant to Section 4127.1 or 4127.2~~ *compounding injectable sterile drug products* poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from that activity. The cease and desist order shall remain in effect for no

1 more than 30 days or the date of a hearing seeking an interim
2 suspension order, whichever is earlier.

3 (b) Whenever the board orders the closure of a business
4 pursuant to subdivision (a), the board shall immediately issue the
5 owner a notice setting forth the acts or omissions with which the
6 owner is charged, specifying the pertinent code section or sections.

7 (c) The order shall provide that the owner, within 15 days of
8 receipt of the notice, may request a hearing before the president of
9 the board to contest the closure order. Consideration of the owner's
10 contest of the closure order shall comply with the requirements of
11 Section 11425.10 of the Government Code. The hearing shall be
12 held no later than five days from the date the request of the owner
13 is received by the board. The president shall render a written
14 decision within five days of the hearing. In the absence of the
15 president of the board, the vice president of the board may conduct
16 the hearing permitted by this subdivision. Review of the decision
17 of the president of the board may be sought by the owner or person
18 in possession or control of the pharmacy pursuant to Section
19 1094.5 of the Code of Civil Procedure.

20 (d) Failure to comply with a closure order issued pursuant to
21 this section shall be unprofessional conduct.

22 4127.4. Notwithstanding any other provision of law, a
23 violation of this article, or regulations adopted pursuant thereto,
24 may subject the person or entity that committed the violation to a
25 fine of up to two thousand five hundred dollars (\$2,500) per
26 occurrence pursuant to a citation issued by the board.

27 4127.5. The fee for the issuance of a license, or renewal of a
28 license, to compound sterile drug products shall be five hundred
29 dollars (\$500) and may be increased to six hundred dollars (\$600).

30 SEC. 4. No reimbursement is required by this act pursuant to
31 Section 6 of Article XIII B of the California Constitution because
32 the only costs that may be incurred by a local agency or school
33 district will be incurred because this act creates a new crime or
34 infraction, eliminates a crime or infraction, or changes the penalty
35 for a crime or infraction, within the meaning of Section 17556 of
36 the Government Code, or changes the definition of a crime within
37 the meaning of Section 6 of Article XIII B of the California
38 Constitution.

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